
# State and Federal Regulatory Requirements

Basics of Infection Prevention
2-Day Mini-Course
October-November 2011

# Objectives

- List national, state and local regulatory bodies that oversee infection prevention
- Describe policy decisions and requirements for public reporting of HAI
- Discuss interpretation of California statutes and regulations
- Review current infection control-related regulations

# THE AGENCIES



# Health Care Regulatory Agencies

| National | State-level | Local |
|---|---|---|
| Centers for Medicare & Medicaid Services (CMS) | California Department of Public Health<br>• Licensing & Certification<br>• Reportable Diseases and conditions<br>• Medical Waste Program | Your local Health Officer and Health Department |
| Occupational Health and Safety Administration (OSHA) | Cal-OSHA | Environmental Health<br>Communicable Diseases reporting |

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# Centers for Medicare & Medicaid Services (CMS)

- CMS provides health insurance through Medicare, Medicaid
- Social Security Act (SSA) requires meeting Conditions of Participation (COP) in order to receive Medicare and Medicaid funds
  - SSA Section 1861
- “Surveys and certifies” health care facilities (including nursing homes, home health agencies, and hospitals)
  - DHHS requires that state health agencies enforce

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# Licensing and Certification (L&C)

- Headquarters - Sacramento, CA
- 13 District Offices plus LA County (5)
- 600+ Health Facility Evaluator Nurses
- License over 30 different facility types, including
  - GACH (general acute care hospitals)
  - SNF
  - Primary Care Clinics
  - Ambulatory Surgery Centers

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# Accreditation Agencies

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO -> **TJC**)

- Private, independent accreditation organization with standards
- Certifies compliance with CMS requirements

Ambulatory Surgery Center Certification

- American Association of Ambulatory Surgery Centers (AAASC)
- American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)

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# Relationships

- TJC certifies ("Deems") to CMS that GACH licensed in California meets federal requirements
  - 80% hospitals TJC accredited
- Otherwise, State Agency (L&C) certifies to CMS
- Consolidated Accreditation and Licensing (CALS) surveys – jointly with TJC
- L&C surveys enforce state laws (e.g. SB 1058) and regulations (CCR Title 22)

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# What is the PSLS?

- GACH Survey to determine compliance with Statutes enacted since 2006.
  - End of Life Care
  - Brain Death
  - Hospital Services
  - Patient Safety & Infection Control
  - Discharge Planning
  - Dietary
  - Immunizations
  - Fair Pricing




AFL 11-01 Patient Safety Licensing Survey, www.cdph.ca.gov/PROGRAMS/LNC/Pages/PSLS

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# Non-Regulatory "Influencers"

- Centers for Disease Control and Prevention (CDC)
  - HICPAC: Healthcare Infection Control Practices Advisory Committee
  - NHSN: National Healthcare Safety Network
- Institute for Healthcare Improvement (IHI)
- National Quality Forum (NQF)
- Professional organizations and societies (SHEA, APIC, CSTE, IDSA)

# THE POLICIES

# Increasing Expectation for HAI Prevention

1999 - Institute of Medicine published “To Err is Human”

- Began patient safety movement by highlighting errors and death occurring in hospitals

2005 - Budget Reconciliation Act - Non-payment for ‘preventable’ infections

- Mediastinitis after CABG, CLABSI CAUTI, SSI after hip arthroplasties

2006 and 2008 - CA Legislature passed and governor signed into law requirements for public reporting of HAIs

2009 – U.S. Health and Human Services (HHS) released an HAI prevention action plan with measurable 5-year goals

2010 - CMS Inpatient Prospective Payment System (IPPS)

- Specified reporting of HAI infections through NHSN
- Value-based purchasing
  - Initially reimbursing hospitals for reporting
  - Transitioning to pay for performance if quality targets met

Mar 2010 - Patient Protection and Affordable Care Act (ACA)

- Extends health care coverage to more Americans
- Various strategies to improve care quality, while decrease
  - FY 2013 – reimbursement for CLABSI reductions
  - FY 2014 – reimbursement for SSI reductions

# Demand for HAI Transparency

- Public disclosure intended as driver for infection prevention; encourages healthcare providers to take action
- Public reporting favored by consumers as means to assess quality of healthcare
- Better informed public can drive demand for higher quality healthcare
- Assumption:  lower costs to hospitals and society

# HAI Reporting to CMS via NHSN – Current and Proposed Requirements

8/1/2011

| HAI Event | Facility Type | Start Date |
|---|---|---|
| CLABSI | Hospitals, All ICUs (Adult, Peds, NICU) | January 2011 |
| CAUTI | Hospitals, Adult and Pediatric ICUs | January 2012 |
| SSI | Hospitals, Colon surgery, Abd hyst | January 2012 |
| I.V. antimicrobial start *(proposed)* | Dialysis Facilities | January 2012 |
| Positive blood culture *(proposed)* | Dialysis Facilities | January 2012 |
| Signs of vascular access inf *(proposed)* | Dialysis Facilities | January 2012 |
| CAUTI | Inpatient Rehabilitation Facilities | October 2012 |
| CLABSI *(proposed)* | Long Term Care Hospitals | October 2012 |
| CAUTI *(proposed)* | Long Term Care Hospitals | October 2012 |
| MRSA Bacteremia | Acute Care Hospitals, Facility-wide | January 2013 |
| *C. difficile* LabID Event | Acute Care Hospitals, Facility-wide | January 2013 |
| HCW Influenza Vaccination | Acute Hospitals, OP Surgery, ASCs | January 2013 |
| SSI *(proposed)* | Outpatient Surgery/ASCs | January 2014 |

# 2009 HHS Action Plan HAI Reduction Targets

| Metric | Data | Target |
|---|---|---|
| Central line bloodstream infections | NHSN | ↓ 50% |
| Adherence to central line insertion practices | NHSN | 100% |
| Hospitalizations with *Clostridium difficile* | Admin | ↓ 30% |
| *Clostridium difficile* infections | NHSN | ↓ 30% |
| Catheter-associated urinary tract infections | NHSN | ↓ 25% |
| MRSA incidence rate (healthcare-associated) | EIP | ↓ 50% |
| MRSA bacteremia (healthcare facility-wide) | NHSN | ↓ 25% |
| Surgical site infections | NHSN | ↓ 25% |
| Surgical Care Improvement Program adherence | SCIP | 95% |

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2011 Progress towards goals: **Green=**on target,
**Red=**needs more attention
**Black=**data not yet available

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# FEDERAL REGS

# Finding Federal Regulations

Centers for Medicare and Medicaid Services (CMS)

http://www.cms.hhs.gov/

- Regulations & Guidance

  http://www.cms.hhs.gov/home/regsguidance.asp

  - Hospital Center

    http://www.cms.hhs.gov/center/hospital.asp

  - Conditions of Participations (CoPs)

    http://www.cms.hhs.gov/CFCsAndCoPs/06_Hospitals.asp

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# Federal CMS Title 42 Regulations

Subchapter G  Standards and Certification

- Part 482  Conditions of Participation For Hospitals
  - 482.42 Condition of Participation: Infection Control
- Part 483  Requirements For States And Long Term Care Facilities
- Part 484  Home Health Services
- Part 493  Laboratory Requirements
- Part 494  Conditions for Coverage for End-stage Renal Disease Facilities

# Part 42 Subpart C - Basic Hospital Functions

§ 482.21 Quality Assurance
§ 482.22 Medical Staff
§ 482.23 Nursing services
§ 482.24 Medical record services
§ 482.25 Pharmaceutical services
§ 482.26 Radiologic services
§ 482.27 Laboratory services
§ 482.28 Food and Dietetic services
§ 482.31 Utilization review
§ 482.41 Physical environment
**§ 482.42 Infection Control**
§ 482.43 Discharge planning
§ 482.45 Organ, tissue, and eye procurement

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# CMS CoP Interpretive Guidelines for Infection Control – **READ THEM!**

- Hospitals must be sanitary
- Have active IC Program and someone overseeing it
- Surveillance must be systematic
    - Infections must be “logged”
- Leadership must
    - Ensure problems identified by IC are addressed
    - Take responsibility for corrective action plans when problems identified

Complete interpretive guidelines (14 pages) on APIC website. Google “APIC interpretive guidelines”

# Part 43 Subpart B - Requirements for Long Term Care Facilities

§ 483.1 Basis and scope.
§ 483.5 Definitions.
§ 483.10 Resident rights.
§ 483.12 Admission, transfer and discharge rights.
§ 483.13 Resident behavior and facility practices.
§ 483.15 Quality of life.
§ 483.20 Resident assessment.
§ 483.25 Quality of care.
§ 483.30 Nursing services.
§ 483.35 Dietary services.
§ 483.40 Physician services.
§ 483.45 Specialized rehabilitative services.
§ 483.55 Dental services.
§ 483.60 Pharmacy services.
**§ 483.65 Infection control.**
§ 483.70 Physical environment.
§ 483.75 Administration.

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# The Joint Commission National Patient Safety Goal (NPSG) 7: Reduce Risk of HAI

- NPSG.07.01.01: Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.
- NPSG.07.03.01: Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals.
- NPSG.07.04.01: Implement evidence-based practices to prevent central line-associated bloodstream infections.
- NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections.
- NPSG.07.06.01*: Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).

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# CALIFORNIA REGS

# California HAI Prevention Activities Timeline

2003 - Little Hoover Report

2005 - HAI Advisory Working Group "White Paper"

2006 - SB 739 passed

2007 - HAI-Advisory Committee formed

2008 - Start of mandatory reporting of CLIP through NHSN
- SB 1058, 158 passed

2009 - SB 1058/158 take effect
- H1N1 pandemic
- Startup of CDPH HAI Program, Dec 9

2010 - Startup of HAI Infection Prevention Liaison Program (ARRA funded)
- HAI reporting thru NHSN, Apr
- CMS IPPS Rule

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# Finding California Laws, Regulations

Office of Administrative Law (OAL) Website

http://www.oal.ca.gov/

Sponsored Links *

- Cal. Code Regs
- Legislative Information
- California Codes

* Not maintained by OAL

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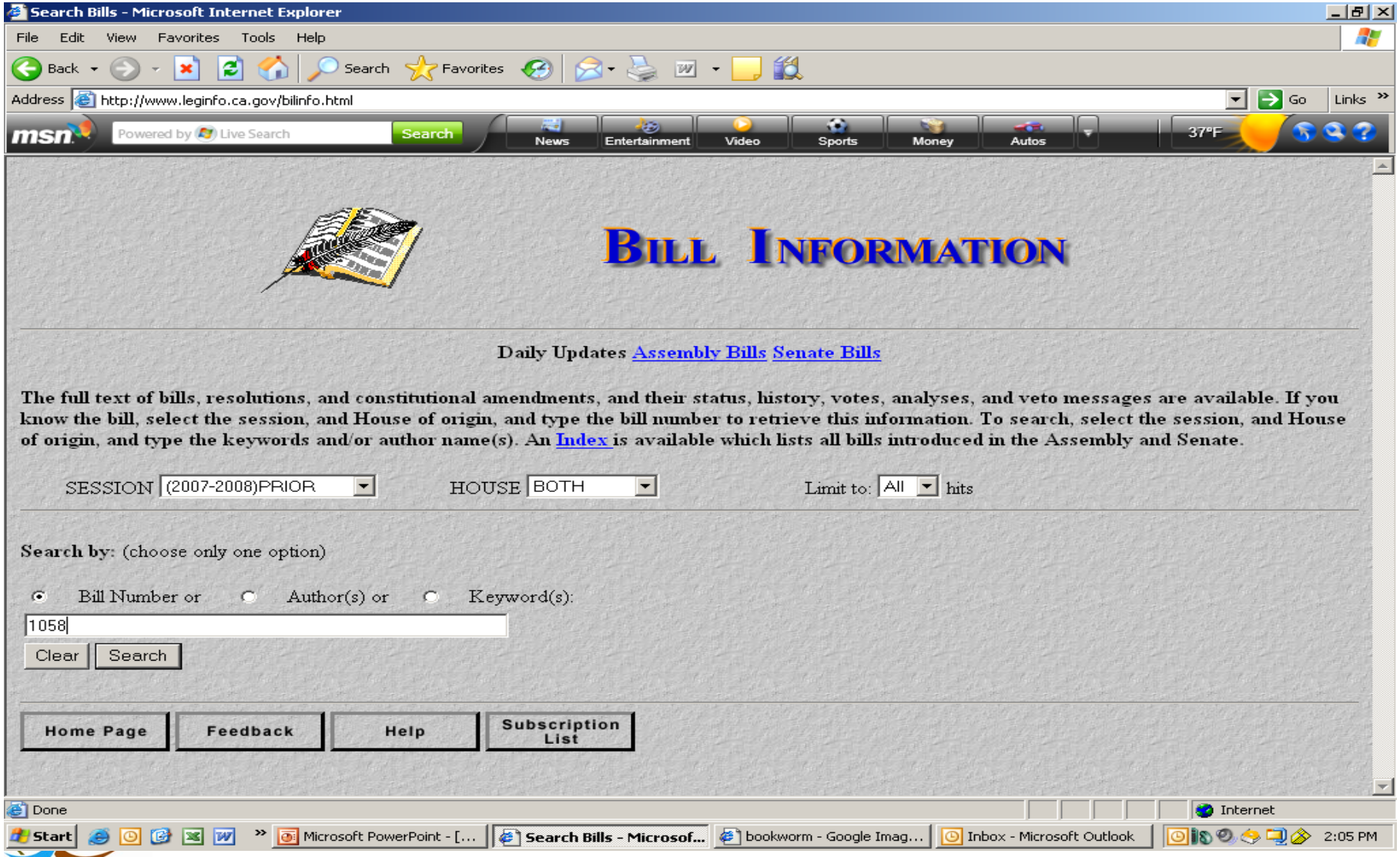


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www.leginfo.ca.gov

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# Terminology

The California legislature passes **Bills**

- Bills make findings and declarations, and declare intent
- Words to look for when reading Bills
  - "Shall" – requires someone to do something
  - "May" – authorizes someone to do something
  - "Shall not" – prohibits someone from doing something

Legislative bills set **Statute**

# Terminology - 2

**Regulations**

1. **Carry-out** promulgation of what a Bill authorizes or directly requires a Department of the State to do
2. **Clarify** the requirements of a Bill (far less common)

# Terminology - 2

**All Facilities Letters (AFL)**

- Purpose: To inform facilities of a new requirement or a change of requirement
- Usually incorporates language from the legislation
- The absence of an AFL does not absolve a facility from complying with the law

Note: When enforcing, L&C is not allowed to interpret legislation in a manner that would expand or contract its meaning

# California Title 22 Regulations

Division 5 Licensing and Certification of Health Facilities

- Chapter 1 GACH (General Acute Care Hospital)
  - Article 7 Administration
- Chapter 2 Acute Psychiatric Hospital
- Chapter 3 Skilled Nursing Facilities
- Chapter 4 Intermediate Care Facilities
- Chapter 7 Primary Care Clinics
  - Chapter 7.1 Specialty Clinics
    - Article 6. Hemodialyzer Reuse
- Chapter 12 - Correctional Treatment

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# California Code of Regulations – Title 22*

- Requires a written hospital infection control program for the surveillance, prevention, and control of infections.
- Policies and procedures must cover
  - Management of transmission risks within hospital
  - Education
  - A plan for surveillance, including management of outbreaks
  - How to identify biohazardous equipment and materials
- Oversight of the program is vested in a multidisciplinary committee
- There shall be one designated FTE/200 licensed beds

*Title 22, Div 5, Chap 1, Article 7, Sec 70739

# Reportable Diseases and Conditions

- All cases of reportable diseases shall be reported to the **local health officer** in accordance with Section 2500, Article 1, Subchapter 4, Chapter 4, Title 17, California Administrative Code
- Defined as events that threaten welfare, safety, or health of patients, personnel, or visitors

Title 17, California Code of Regulations (CCR) §2500, §2593, §2641.5-2643.20, and §2800-2812 Reportable Diseases and Conditions*

§ 2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.

- § 2500(b) It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or condition listed below, to report to the local health officer for the juridiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.
- § 2500(c) The administrator of each health facility, clinic, or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.
- § 2500(a)(14) "Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

URGENCY REPORTING REQUIREMENTS [17 CCR §2500(h)(i)]

✆ ! = Report immediately by telephone (designated by a ♦ in regulations).
† = Report immediately by telephone when two or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a ● in regulations.)

# Senate Bill 739 Requirements*

HSC 1288.6 – Implement policies to prevent CLABSI… in ICUs

HSC 1288.7

- Annually offer influenza **vaccination to employees**
- Institute **respiratory hygiene** and cough etiquette protocols
- Develop capacity to **isolate influenza patients**
- Develop **seasonal influenza plan…**collaboration with public health in event of a pandemic

*Health & Safety Code Chapter 2, Division 2

# SB 739 Requirements - 2

HSC 1288.8

- Develop a process for **evaluating the judicious use of antibiotics**
- Report specified process measures through NHSN (Report **CLIP** from ICU)

HSC 1288.9

- Develop and report compliance with measures for prevention of SSI (**SCIP**)
- Develop and implement policies and procedures to **prevent VAP**

# Senate Bill 158 Requirements

HSC 1279.6* – Hospitals must have a **patient safety plan**…encourages a **culture of safety**

HSC 1279.7* – Hospital must have a **hand hygiene program**

HSC 1288.6 – 3-year **evaluation of IP program**, including program resources. Updated annually

HSC 1288.95 – Staff **education**, including IC Chair, clinicians, hospital staff, and housekeeping

*Applies to general acute care, acute psychiatry, skilled nursing facilities, and specialty hospitals (e.g., maternal-child)

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# Senate Bill 1058 Requirements

HSC 1255.8 – **MRSA testing** of specified patients, timely patient education, re-testing of negative patients prior to discharge

- Delineates specifics for cleaning... include in infection control policy
- Infection control officer to head IC efforts; name publicly available upon request

HSC 1288.55

- Reporting **MRSA/VRE BSI**, **C. diff infections**
- **SSI** from ”deep and organ/space surgical sites, cardiac, orthopedic, and gastrointestinal” surgical procedures

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# Cal/OSHA

Department of Industrial Relations -->
Division of Occupational Safety and Health -->
Cal/OSHA

- Develops regulations for workplace safety and health
  - Standards Board adopts
- California regulations must be “at least as effective” as federal regulations

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# Cal-OSHA Bloodborne Pathogens (BBP) Standard*

Purpose: Ensure employees are protected from potential exposure to blood/body fluids

Includes

- Hierarchy of controls (early identification, engineering controls, administrative policies, personal protective equipment)
- Safe practices, risk assessment, medical surveillance of employees
- HBV offered to all employees at risk
- Post exposure management
- Training and record keeping

In 1999: strengthened sharps protection language, sharps injury log, HCV as BBP

*CCR, Title 8, Section 5193

# Cal-OSHA Aerosol-Transmissible Diseases Standard (ATD)*

Inclusive of any disease that could be "transmitted by particles flying through air and landing in the lungs or on mucous membranes"

- Aerosol, near-aerosol, droplet modes of transmission
- Tuberculosis Standard rolled into this

Extends scope of requirement for to settings outside hospital – across continuum

- Requires specified levels of respiratory protection for certain diseases (be familiar w/ appendices)

Format, requirements similar to BBP Standard

*CCR, Title 8, Section 5199

# Cal-OSHA Respiratory Protection Standard*

Requires employer to have a Respiratory Protection Program

- How to select and care for respirators
- Medical screening
- Fit-testing requirements and methods
- Training and documentation

*CCR, Title 8, Section 5144

# Medical Waste Management Act*

Ensures proper handling and disposal of medical waste throughout California

Biohazardous Waste See HSC 117635 for complete definition

- (a) Laboratory waste, including human or animal specimen cultures from medical and pathology laboratories
- (b) Human surgery specimens or tissue
- (e) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans... that are required to be isolated by infection control staff, attending physician and surgeon, ...or local health officer

*Health and Safety Code 117600

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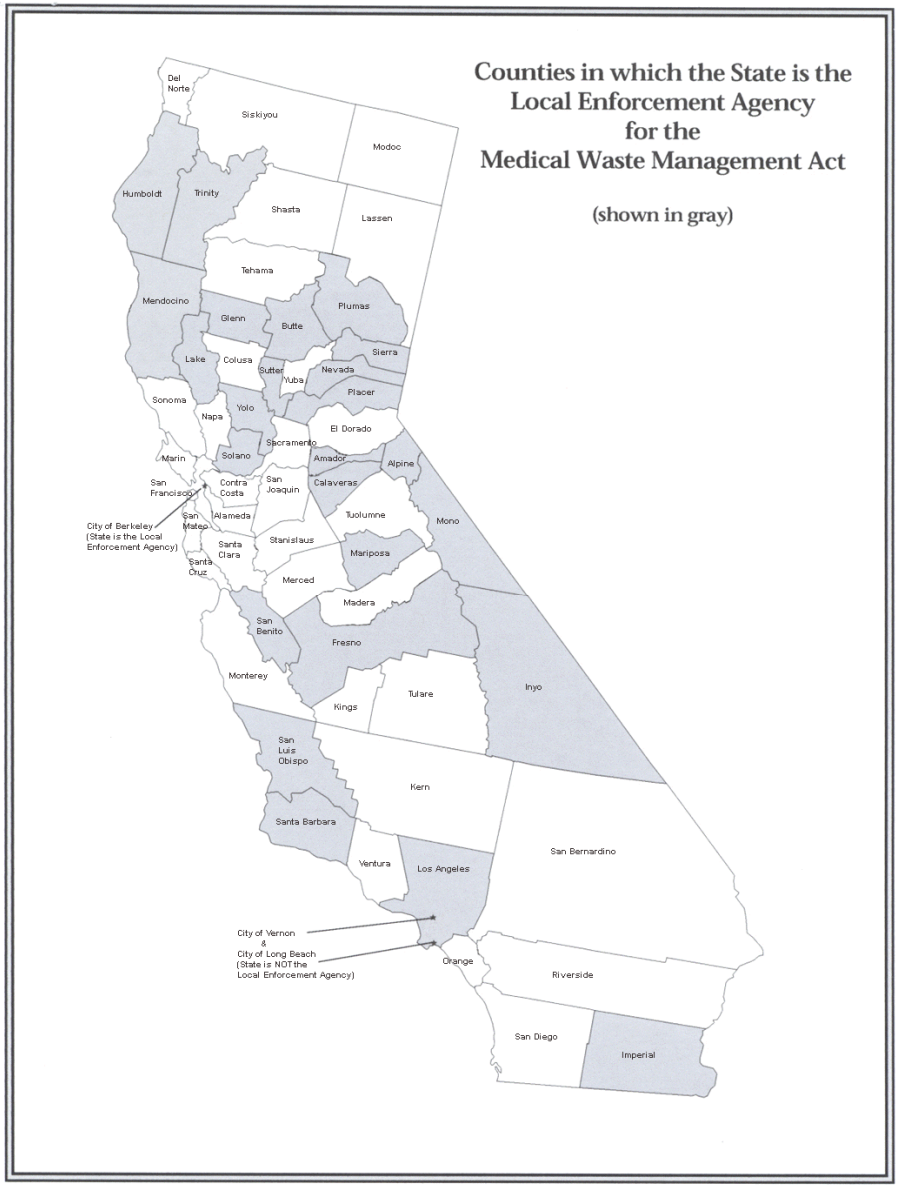
# Medical Waste Management Act -2

Enforced by

- CDPH Medical Waste Program

**-or-**

- Local Departments of Environmental Health



# Regulatory Survival 101

What MUST you do?

- Report what to whom by when?
- Endeavor not to re-invent the wheel
- Continue to breathe (every day)

Work collaboratively; while you may be responsible for the program, others may have easier access to needed pieces of this puzzle

# HAI Prevention Now: A Message of Hope

We no longer accept that 2/3 infections are a cost of receiving healthcare. Infections are ever more the exception, not the expected outcome

We know there are bundles of evidence-based strategies and new technology that, when properly applied, can enhance patient safety

By apportioning (or reapportioning) dollars to buy specified outcomes, the mantras of prevention and patient safety have become a higher priority to healthcare providers

We remain committed to our goal:
healthier, safer patients!

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# Questions?

For more information, please contact any HAI Liaison Team member.

Thank you